DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 7, 2014

Entrotech Life Sciences Incorporated
% Ms. Valerie Defiesta-Ng
Experien Group, LLC
755 North Mathilda Avenue, Suite 100
Sunnyvale, California 94085

Re: K140389
Trade/Device Name: ChloraDerm™ Antimicrobial Transparent Thin Film Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 8, 2014
Received: October 9, 2014

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140389

Device Name
ChloraDerm™ Antimicrobial Transparent Thin Film Dressings

Indications for Use *(Describe)*
The entrotech life sciences inc. ChloraDerm™ Antimicrobial Transparent Thin Film Dressings are intended to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures and wires.

ChloraDerm™ may also be used to cover and secure primary dressings.

ChloraDerm™ inhibits microbial growth within the dressing and prevents external contamination.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Notification K140389

GENERAL INFORMATION

Applicant:
entrotech life sciences inc.
409 Illinois Street
San Francisco, CA 94158
U.S.A.
Phone: 510-384-0657
Fax: 800-580-0161

Contact Person:
Valerie Defiesta-Ng
Regulatory Consultant
Experien Group, LLC
755 N. Mathilda Avenue, Suite 100
Sunnyvale, CA 94085
U.S.A.
Phone: 408-400-0856
Fax: 408-400-0865

Date Prepared: October 7th, 2014

DEVICE INFORMATION

Trade Name:
ChloraDerm™ Antimicrobial Transparent Thin Film Dressings

Generic/Common Name:
Wound Dressing, Antimicrobial

Classification:
Antimicrobial Dressing, Unclassified

Product Code:
FRO

PREDICATE DEVICE(S)

- Covalon SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver ("SurgiClear") (K121819)
- 3M™ Tegaderm™ Transparent Dressings ("Tegaderm") (K973036)

INDICATIONS FOR USE

The entrotech life sciences inc. ChloraDerm™ Antimicrobial Transparent Thin Film Dressings are intended to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures and wires. ChloraDerm may also be used to cover and secure primary dressings. ChloraDerm inhibits microbial growth within the dressing and prevents external contamination.

PRODUCT DESCRIPTION

The entrotech life sciences inc. ChloraDerm™ Antimicrobial Transparent Thin Film Dressings ("ChloraDerm") are intended to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures and wires. The ChloraDerm may also be used to cover and secure primary dressings. The ChloraDerm inhibits microbial growth within the dressing and prevents external contamination. ChloraDerm consists of a transparent, thin plastic film coated with an acrylic-based pressure sensitive adhesive containing chlorhexidine as an antimicrobial agent. The ChloraDerm dressing is a single-use device, intended to be used for up to 7 days.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the ChloraDerm are substantially equivalent to the predicate devices. Table 5.1 lists the technological characteristics of the ChloraDerm and the predicate device and provides the rationale to support a determination of substantial equivalence. Any differences in the technological characteristics of the device do not affect the safety and effectiveness of the device.

Table 5.1: Substantial Equivalence Table

Feature	entrotech life sciences inc. ChloraDerm™ Antimicrobial Transparent Thin Film Dressings	Covalon SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver	3M™ Tegaderm™ Transparent Dressing	Substantial Equivalence Rationale
510(k) Number	K140389	K121819	K973036	--
Instruction for Use	Single Use	Single Use	Single Use	N/A (Same)
Duration of Use	Up to 7 days	Up to 7 days	Up to 7 days	N/A (Same)
Anatomical Site	Surface of skin	Surface of skin	Surface of skin	N/A (Same)
Physical Composition	Polyurethane film	Polyurethane film	Polyurethane film	N/A (Same)
Antimicrobial Agent	Chlorhexidine in the adhesive	Chlorhexidine and Silver salts in the adhesive	None	Antimicrobial Efficacy Testing- All acceptance criteria were met and the device performed as intended establishing antimicrobial effectiveness.
Adhesive	Acrylic-based pressure sensitive adhesive	Silicone-based pressure sensitive adhesive	Acrylic-based pressure sensitive adhesive	Physical Performance Testing- All acceptance criteria were met and the device performed as intended.
Design Features	Transparent for site visibility, Framed Delivery System	Transparent for site visibility, Pull away release tabs for delivery	Transparent for site visibility, Framed Delivery System	N/A (Same)
Dimensions	1624CH: 2-3/8” x 2-3/4” 1626CH: 4” x 4-3/4”	TWBD1017: 1.6” x 2.8” TWBD1018: 1.6” x 5” TWBD1019: 4” x 4.8” TWBD1021: 1.6” x 1.6” TWBD1023: 2.5” x 8” TWBD1024: 2.6” x 10” TWBD1025: 2.5” x 12”	Multiple sizes/Multiple Part Numbers	The dimensional differences raise no new issues of safety or efficacy.

Feature	entrotech life sciences inc. ChloraDerm™ Antimicrobial Transparent Thin Film Dressings	Covalon SurgiClear™ Antimicrobial Clear Silicone Adhesive Dressing with Chlorhexidine and Silver	3M™ Tegaderm™ Transparent Dressing	Substantial Equivalence Rationale
Sterility	Gamma	Ethylene Oxide	Radiation	Sterilization validation performed, ensures a SAL of 10^{-6} as per device specifications.
Target Microbes	Gram-positive bacteria, Gram-negative bacteria and yeast including: • Methicillin-Resistant *Staphylococcus aureus (MRSA)* • Methicillin-Resistant *Staphylococcus epidermidis (MRSE)* • Vancomycin-Resistant *Enterococcus faecalis (VRE)* • Multiple Drug-Resistant *Enterococcus faecium (MDR)* • *Enterococcus faecium* • *Pseudomonas aeruginosa* • *Escherichia coli* • *Serratia marcescens* • *Candida albicans* • *Candida tropicalis* • *Candida parapsilosis*	Gram-positive bacteria, Gram-negative bacteria and yeast including: • Methicillin-Resistant *Staphylococcus aureus (MRSA)* • Methicillin-Resistant *Staphylococcus epidermidis* • Vancomycin-Resistant *Enterococcus faecalis (VRE)* • *Klebsiella pneumoniae* • *Pseudomonas aeruginosa* • *Enterobacter cloacae* • *Candida albicans* • *Candida tropicalis*	Not specified on IFU	Antimicrobial Efficacy Testing- All acceptance criteria were met and the device performed as intended establishing antimicrobial effectiveness.

SUBSTANTIAL EQUIVALENCE

The indications for use of the ChloraDerm is identical to that of the Covalon SurgiClear predicate device. All three devices are intended to cover and protect wounds caused by percutaneous medical devices and are also to be used as a secondary dressing to cover and secure a primary dressing.

The ChloraDerm is similar to the Tegaderm in its physical performance and to the SurgiClear in its antimicrobial efficacy. Available performance data support the determination of substantial equivalence in terms of both device physical performance and antimicrobial efficacy and confirmed that any differences in the technological characteristics between the ChloraDerm and the predicate devices do not raise any new issues of safety or effectiveness. Thus, the ChloraDerm is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing including head-to-head comparison testing with the predicate devices was conducted on the ChloraDerm to support a determination of substantial equivalence to the predicate devices. The following table lists the non-clinical testing performed and the results for each test.

Test Type	Test Description	Results
Physical Performance	Water Vapor Transmission Rate	The ChloraDerm passed all functional testing and met all product specification requirements in addition to demonstrating equivalent performance to that of the predicate device.
	Flammability	
	Synthetic Blood Penetration	
	Viral Penetration	
	Tear Resistance	
	Tensile Elongation Recovery/Elongation to Break	
	Primary Release	
	Peel Adhesion/Shear Adhesion	
Antimicrobial Efficacy	Zone of Inhibition/Activity Spectrum	The ChloraDerm demonstrated that it had adequate antimicrobial activity that was equivalent to that of the predicate device.
	In vitro Kill Time	
Analytical	*p*-Chloroaniline (PCA) Content	The test results from zero-time and accelerated aged samples demonstrated that no detectable levels of *p*-chloroaniline were observed in the ChloraDerm. However, *p*-chloroaniline was detected in all of the Covalon SurgiClear samples evaluated.

In addition to the above performance testing, entrotech conducted Biocompatibility, Shelf life, Packaging and Sterilization Validation testing on the ChloraDerm.

The collective results of the performance testing demonstrate that the materials chosen, manufacturing processes, and design of the ChloraDerm meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the ChloraDerm does not raise new questions of safety or effectiveness when compared to the predicate devices.

CONCLUSION

The entrotech life sciences inc. ChloraDerm is substantially equivalent to the Covalon SurgiClear and 3M Tegaderm dressings. The indications for use of the ChloraDerm is identical to that of the Covalon SurgiClear predicate device. The product performance testing demonstrated that ChloraDerm is as safe, as effective and performs as well as the predicate devices in terms of intended use, safety and technological characteristics, and patient populations. The key difference between the devices is the presence and/or choice of antimicrobial agent that is incorporated into the adhesive. The difference in antimicrobial agent between the subject device and the SurgiClear predicate device raises no issue of safety and effectiveness. Additionally, the difference in physical performance between the subject device and the 3M Tegaderm product raises no issues of safety and effectiveness. The information contained in this 510(k) premarket notification demonstrates the substantial equivalence of the ChloraDerm to the SurgiClear and to the Tegaderm.